

Washington State University Human Research Protection Program (HRPP)

Office of Research Assurances, PO Box 643143 Neil 427

Pullman, WA 99164-3143

Telephone: (509)335-7646 Email: irb@wsu.edu Web site: www.irb.wsu.edu

**Human Subjects Research Determination Form**

**NOTE: NOT HUMAN SUBJECTS RESEARCH DETERMINATION (NHSR) IS NOT IRB APPROVAL. PLEASE REMOVE ANY LANGUAGE REFERENCING IRB APPROVAL FROM THE STUDY MATERIALS.**

*Instructions:*

* + - * *Note: This application is not required for departments that have developed their own procedures for NHSR determinations (e.g. program evaluation or quality improvement projects).*
      * *For Departments that do not have an alternate procedure, The PI or WSU HRPP will determine if your project meets the federal definition(s) of human subject research or qualifies for exemption from IRB review. Do not begin data collection prior to NHSR Determination.*
      * *Projects that are determined as NHSR are exempt from federal regulations, however, they are not exempt from ethical standards as outlined in the* [*Belmont Report*](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/)*. This means, for example, that if potential subjects will be interviewed in a project that is determined as NHSR, they must be fully informed and free to choose whether or not to participate.*
      * *Any changes in the projects determined as NHSR should be reassessed to ensure that the projects can still meet that determination.*
      * *Institutional policies will still apply to NHSR projects. (e.g. EP #8, Data Retention BPPM 90.01, etc.)*

**SECTION 1. GENERAL INFORMATION**

1. Principal Investigator (PI) Contact Information:

(***PI must be WSU faculty or staff****, and will be the study supervisor at WSU.* ***Students, post-doctoral researchers, and visiting faculty may not serve as PI****. All correspondence will be directed to the PI listed below*.)

Last Name: Hagen First Name: Edward WSU ID #: 11019788 Position: Professor

Department: Anthropology College/Area: CAS Campus: Vancouver

Phone: 6-9257 E-mail: edhagen@wsu.edu

1. Study Title: Depression, health, and gender (NHANES)
2. Please provide a brief description of your project (ex: what data you will be collecting, how you will be collecting the data, etc.): Data are deidentified and publicly available for download, and were collected by the Centers for Disease Control and Prevention (CDC) for the National Health and Nutrition Examination Survey (NHANES). The NHANES survey collects data on a variety of health and demographic factors from a nationally representative sample in the United States. The NHANES interview includes demographic, socioeconomic, dietary, and health-related questions. The examination component consists of medical, dental, and physiological measurements, as well as laboratory tests. IRB approval was granted for each phase of the survey (IRB/ERB Protocols 98-12, 2005-06, 2011-17). Our study aims to better understand the relationship between depression and other factors such as age, health, sexual behavior, parity, social support, and socioeconomic factors. Depression is a health burden that affects women and men across the globe, yet its risk and protective factors are still not well understood. Research in this area may yield further information on the causes and outcomes of depression which could inform health and outreach programs aimed at treatment and prevention.
3. Is this a student’s project in which you are serving as a mentor?

Yes  No

1. Please indicate if you require a determination letter (evidence of ethics review) for publication, grant submission or other purposes. You will still be notified of the determination via email but a letter will be attached if you select “yes”.

Yes  No

*NOTE: Some CITI Training may be required. (e.g. Responsible Conduct of Research or NIH Good Clinical Practice (GCP))*

**SECTION 2. SCREENING QUESTIONS for REVIEW DETERMINATION**

*45 CFR 46.102 (l): “Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”*

*Note: The* [*Revised Common Rule*](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML) *(2018 requirements) adds a provision that identifies four types of activities as not being “research” as defined in the Rule. In other words, the Revised Common Rule does not apply to the following types of activities because they do not meet the regulatory definition of research:*

* *Certain scholarly and journalistic activities,*
* *Certain public health surveillance activities,*
* *Collection and analysis of information, specimens, or records, by or for a criminal justice agency for certain criminal justice or investigative purposes, and*
* *Certain authorized operational activities for national security purposes*

**Consider the regulatory definition and guidance for research (above) and answer the questions below:**

1. Is it systematic; involving a system, method, or plan that will be employed consistently throughout data collection?

Yes  No

1. Will your conclusions be presented as representative of a larger population from which your sample was recruited? (Mark “NO” if the conclusions will apply only to the sample population). Note: publication may be an indicator of contribution to generalizable knowledge, but not all published projects meet the federal definition of research. Please consult the WSU HRPP if you require clarification.

Yes  No

1. Is your study a clinical experiment or investigation (FDA) in which a test article (drug or device) will be administered to human subjects?

Yes  No

**If you answer “NO” to either questions 1 or 2 AND 3 above your study is not research, according to the federal definition(s), and IRB review is not required.**

**If you answer “YES” to both questions 1 and 2 OR 3 above, your study is research. Please complete questions 3-6 below.**

45 CFR 46.102 (e)(1)*: “Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”*

1. Does your research involve one or more living individuals?

Yes  No

**If yes, answer questions 5-7.**

**If no**, your project does not involve human subjects according to the definition in 45CFR46.102(e)(1), **do not answer question 5-7.** Keep a copy of this form for your records.

1. Will you obtain information or biospecimens through intervention\* or interaction\* with the

individual and use, study or analyze the information or biospecimens:

Yes  No

1. Will you obtain and use, study, analyze or generate identifiable private information or

identifiable biospecimens (note: intervention or interaction with an individual are not required to meet this criteria).

Yes  No

1. Will the subject receive a test article or act as a control during a clinical trial or clinical investigation (FDA)?

Yes  No

**If you answer “NO” to question 4 your research does not involve human participants and IRB review is not required.**

**If you answer ”YES” to question 4 but answer “NO” to questions 5, 6 and 7, your research does not involve human participants and IRB review is not required.**

**If you answer “YES” to question 3 and to either question 4 or 5, your research involves human participants and you must complete either an Exempt\*\* or Non-Exempt Application. Forms are available here:** [**http://www.irb.wsu.edu/forms.asp**](http://www.irb.wsu.edu/forms.asp)

\*According to 45CFR46.102(2): Intervention includes both physical procedures by which information or biospecimens are gathered (e.g. venipuncture) and manipulations of the subject or the subject’s environment that are for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

For more information please contact the WSU HRPP or refer to [Title 45 Part 45 Section 102 (Definitions)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1102) and CFR 56.102 and 50.3 (FDA definitions).

\*\*Federal regulations specify that certain types of research pose low risk to participants, and therefore may qualify for exemption under federal regulations.